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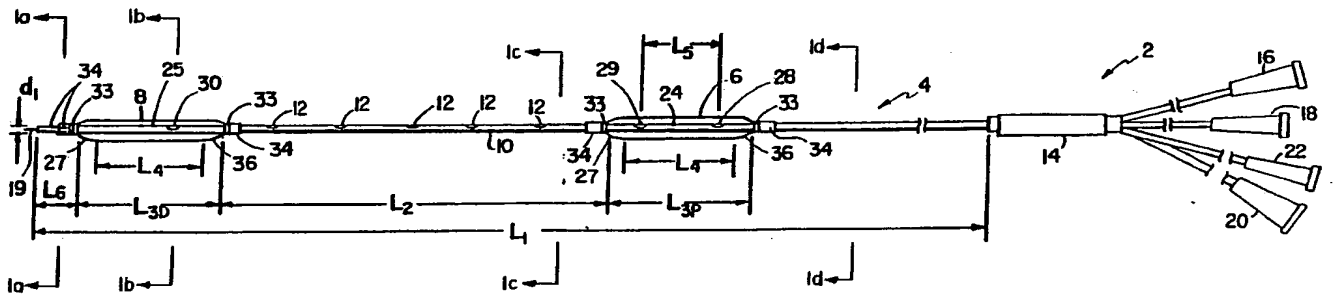
(54) Title: ANGIOPLASTY CATHETER



(57) Abstract

Method and apparatus for treatment of chronic arterial occlusion by combined transluminal angioplasty and topically enclosed thrombolytic enzyme (e.g. recombinant human type plasminogen activator) with the use of a multilumen catheter (4). The catheter has a pair of balloons (6, 8) spaced apart to define a treatment region therebetween, and the intermediate portion (10) of the catheter body defines a plurality of flushing ports (12) in the treatment region. Fibrinolytic agent, e.g. rt-PA, is delivered into the treatment region, and removed from the treatment region, through the flushing ports.

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ANGIOPLASTY CATHETER

Background of the Invention

This invention relates to angioplasty and thrombolysis. Occlusion of blood vessels, e.g., by calcification or thrombus, can lead to serious health consequences. To remove an obstruction, it was proposed by Dotter & Judkins in 1964 to introduce a dilatation catheter. The balloon may be inflated at the point of occlusion to hydraulically dilate the afflicted area. After deflation of the balloon, the catheter is removed and hemostasis is achieved. In 1974, Gruntzig & Hopff proposed to improve this percutaneous transluminal angioplasty technique (PTA) by constructing a cylindrical, single-balloon catheter in which the balloon was of nondistensible material and would expand only to a predetermined diameter, even at very high pressures. Hydraulic inflation of the balloon served to treat the arterial stenosis and thrombosis, and occlusions could be dilated or recanalized to the diameter of the artery above and below the lesion. The balloon was mounted on a 7 French (2.3 mm diameter) shaft, so hematosis after arterial puncture was held a minor problem.

Summary of the Invention

According to one aspect of the invention, a method of treating a chronic occlusion in a blood vessel comprises providing a dilatation catheter having at least two spaced apart inflatable balloons, at least one of which is constructed to serve as a dilatation balloon, the catheter having means to separately inflate each balloon, inserting the catheter in the blood vessel and positioning the catheter so that the dilatation balloon corresponds to the region of the obstruction, inflating the dilatation balloon under conditions to cause dilatation of the thrombosed

stenosed occlusion and exposure of dilated tissue while another balloon is not inflated to dilatation conditions, deflating the dilatation balloon and repositioning the catheter so that one of the balloons lies distal of and at least one other balloon lies proximal of the site at which dilatation has been performed, inflating both balloons sufficiently to isolate the dilated region from systemic blood flow, introducing via a lumen in the catheter, a bolus containing a fibrinolytic agent to the isolated space between the balloons, thus treating the dilated tissue with the agent to reduce the risk of clot formation or restenosis, and thereafter deflating the balloons and removing the dilatation catheter from the body.

In preferred embodiments of the method, the fibrinolytic agent is rt-PA.

According to another aspect of the invention, a dilatation balloon catheter adapted to be advanced through a passageway of a patient's body to the site of an occlusion comprises an elongated, flexible catheter body having a distal region and a proximal end portion, and defining a plurality of lumens, a first inflatable balloon disposed about the catheter body in the distal region, the first balloon formed of a nondistensible material, a second inflatable balloon disposed about the catheter body and spaced proximally of the first balloon, the catheter body and the balloons defining a treatment region generally between the first balloon and the second balloon, a first lumen extending through the catheter body from an opening in the proximal end portion of the catheter body outside the patient's body to an opening within the first balloon, means associated with the first lumen for delivering inflation fluid under pressure through the first lumen into the first balloon for inflation of the first balloon to a maximum

predetermined diameter for dilatation treatment of a wall of a surrounding passageway, a second lumen extending through the catheter body from an opening in the proximal end portion of the catheter body outside the patient's body to an opening within the second balloon, means associated with the second lumen for delivering fluid under pressure through the second lumen into the second balloon for inflation of the second balloon to engage a wall of a surrounding passageway, the catheter adapted to be positioned in a passageway with an occlusion, first subjected to dilatation treatment by inflation of the first balloon, disposed in the treatment region between the balloons, the first balloon and the second balloon adapted to be inflated to engage the wall of a surrounding passageway, thereby to isolate the occlusion in the treatment region, a third lumen extending through the catheter body from an opening in the proximal end portion of the catheter body outside the patient's body to a multiplicity of ports in the treatment region, means associated with the third lumen for delivering a fibrinolytic agent through the third lumen into the treatment region by way of the multiple ports for treatment of the isolated section of the body passageway, and means associated with the third lumen for removal of the fibrinolytic agent from the treatment region through the third lumen by way of the multiple ports.

Preferred embodiments of this aspect of the invention may include one or more of the following features. The catheter body defines a fourth lumen extending through the catheter body from an opening in the proximal end portion of the catheter body outside the patient's body to an opening distal of the distal balloon, the catheter adapted to be advanced through the passageway of the patient's body to the site of an occlusion along a guidewire

extending within the fourth lumen. The fibrinolytic agent is rt-PA.

Objectives of the invention include to provide an improved method and apparatus for treatment of thrombosed vascular occlusions.

These and other features and advantages of the invention will be seen from the following description of a present preferred embodiment, and from the claims.

Description of a Presently Preferred Embodiment

We first briefly describe the drawings.

Fig. 1 is a plan view of an embodiment of an angioplasty catheter apparatus of the invention, while Figs. 1a through 1d are cross sectional views taken at the lines 1a-1a, 1b-1b, 1c-1c and 1d-1d, respectively, along the catheter of Fig. 1; and

Figs. 2 through 2e are somewhat diagrammatic side section views illustrating use of the catheter of the invention.

Referring to Fig. 1, an angioplasty balloon catheter 2 of the invention includes a multi-lumen catheter 4 sized and constructed for introduction into a body lumen. The catheter includes selectively and separately inflatable proximal balloon 6 and distal balloon 8.

The catheter 4 defines four lumens. In a first lumen 62 (Fig. 1a et seq.) extending the length of the catheter resides a guidewire 19 which is typically introduced into the body lumen prior to the catheter to aid steering and positioning of the catheter. The guidewire extends distally from the end 34 of the catheter and proximally beyond connector element 18.

A second lumen 64 (Fig. 1b et seq.) extends through the catheter portion 24 supporting the proximal balloon and

through portion 25 at the distal balloon to terminate at inflation port 30 for introduction and removal of inflation fluid from the distal balloon. A third lumen 68 (Fig. 1d) extends through catheter portion 24 to terminate at inflation ports 28, 29 within the proximal balloon 6 for introduction and removal of inflation fluid from the proximal balloon. Thus the balloons 6, 8 are inflated and deflated by way of separate, noncommunicating catheter lumens. The catheter further defines a fourth lumen 66 Figs. 1c and 1d) that terminates at flushing ports 12 in the catheter central portion 10, between the balloons 6, 8, for introducing and withdrawing lytic enzymes and flushing fluids. At the proximal end of the catheter, generally positioned outside the body when in use, coupling 14 provides access to the multiple lumens of the catheter 4 by a series of separate, connector elements 16, 18, 20, 22, preferably luer lock type connectors, as known.

Inflation of balloons 6, 8 is accomplished by infusion of fluid through connectors 20 and 22, respectively, which communicate with the separate second and third lumens 64, 68. (The second lumen 64 extends longitudinally only to the point of the distal port 29; the third lumen 68 extends longitudinally only to the point of the access port 30.)

Connector 16 allows access to the fourth lumen 66 in communication with the flushing ports 12 between the proximal and distal balloons on the catheter portion 10. Through the flushing ports, a lytic enzyme is passed for the purpose of dissolving thrombi. The fourth lumen 66 extends longitudinally only to the point of the most distal of the ports 12.

The proximal 6 and distal 8 balloons are typically formed of a nondistensible thermoplastic material, e.g. polyolefin or polyester. In this way, the balloon will not exceed a predetermined diameter, usually that of the blood vessel under treatment. The balloons are held fast to the catheter 6 by couplings 34 at the proximal and distal ends. The couplings may, for example, be necked-down portions of the thermoplastic material, melt-bonded or sealably fixed to the catheter 4 using adhesive, as known. Radiopaque markers 33, which are part of or disposed upon the coupling 34, provide means for observing the position of the balloons radiographically.

It is a feature of the balloons that, being nondistensible, the balloons inflate predictably to a uniform size. As will be disclosed further herein, at least one, preferably the distal balloon, is used for angioplasty purposes to break up occlusions prior to dissolving with a lytic enzyme. The balloon for use in angioplasty may be reinforced for added strength. Further, the use of two balloons spaced apart on a single catheter permits the region of thrombus or calcification to be isolated from blood flow after breaking up by angioplasty with a single balloon for the treatment of the afflicted area with a high concentration of enzyme, e.g., 10,000 times the concentration typically given intravenously in treatment of coronary thrombosis. The pressure of the enzyme between the balloons can be made less than that of the surrounding systemic pressure so that, in a case of leakage around the balloons, blood tends to flow into the region of treatment, between the balloons, rather than the enzyme flowing into the bloodstream. This avoids high systemic concentration of the enzyme, which, as known, can cause internal bleeding. (With the segmented treatment, and in spite of the locally

high concentration of enzyme, the total amount is small and will not harm the patient if released into the blood stream.)

In the embodiment shown, the catheter 4 extends a distance, L_1, preferably about 60 to 90 cm, and has a diameter d_1, e.g. about 6 French. The catheter is typically formed of, e.g., polyolefin or polyester. The region of the catheter 10 between the balloons is preferably L_2, about 10 cm, in length. It will be understood that this distance may be different depending on the desired treatment. For example, L_2 may be, e.g., 2 to 50 cm, or, more preferably about 5 to 20 cm, dependent upon the length of the occlusion in the patient to be treated.

The distal balloon 8 has an inflatable length L_{3D}, about 4 cm, and the proximal balloon 6 has an inflatable length L_{3P}, about 2 cm, of which the region of maximum diameter is about L_4, e.g. 3 to 10 mm, or, more preferably, about 5 to 8 mm. The proximal and distal taper region 27, 36 of the balloon is about 5 mm. For the inflation of the proximal balloon 6, a pair of inflation ports 28, 29 may be provided in the catheter portion 24 supporting the balloon. The inflation ports are preferably a distance L_5, about 15 mm apart. The proximal balloon 8 is preferably constructed substantially similar to the distal balloon 6 and positioned on the catheter 4 such that the inflated portion, starting at the distal taper 27, is about L_6, 5 mm, from the most distal tip 34 of the catheter 4. The guidewire 19 is typically of 0.035 inch (0.89 mm) outer diameter. In the preferred embodiment described, the balloons are inflatable to a maximum diameter of about 7 mm.

In the catheter 4, four separate lumens 62, 64, 66, 68 are provided which may extend various lengths within the

catheter and are isolated from each other. The lumen 62 containing the guidewire, accessed through coupling 18, is typically about 0.038 inch (0.97 mm) inner diameter. The lumens communicating with outlets 28, 29 at the proximal balloon (lumen 68), outlet 30 at the distal balloon (lumen 64), and ports 12 between the balloons (lumen 66) are typically about 0.01 inch (0.25 mm) inner diameter. It is important that the lumens are kept separate to allow separate inflation of the proximal and distal balloons, as well as selective introduction of enzyme and introduction and removal of the guidewire.

Referring to Figs. 2 through 2e, use of the catheter according to the invention will be described.

For angioplasty, an occluded vessel 50 is punctured 52 using a needle 54, a shunt or the like. A guidewire 19 is inserted into the vessel and positioned beyond the point of an occlusion 56. The catheter 4, including proximal 6 and distal balloons 8, is fed over the guidewire 19 and positioned within the vessel, the balloons being in the deflated state (Fig. 2).

The physician works the catheter 4 such that the distal balloon 8 is positioned about the occlusion 56 (Fig. 2a). The distal balloon is then dilated by introduction of an inflation fluid, typically an x-ray contrast media, using connector element 22. The fluid flows through an isolated internal lumen 64 within the catheter and exits from the access port 30 to inflate the balloon. The force of the inflating balloon 8 loosens and breaks up the occlusion 56 (Fig. 2b).

The distal balloon 8 is then deflated by withdrawal of the inflation fluid. The catheter 4 is advanced in the

vessel such that the occluded or dilated area 56 is between the proximal balloon 6 and the distal balloon 8 (Fig. 2c).

Balloons 6, 8 are then inflated to isolate the occlusion 56. The distal balloon is inflated as described above. To inflate the proximal balloon, inflation fluid is introduced through connector 20 which accesses an isolated catheter lumen 68. The fluid exits the lumen through ports 28, 29 which access the lumen and allow inflation. The balloons may be inflated simultaneously or serially and the pressure in the region between the balloons measured by an outside gauge attached at connector 16 via a three-way stopcock (not shown). The region is isolated when the pressure reading is less then the systemic pressure with no or slight pulsations.

A solution including a lytic enzyme is then introduced through using coupling means 16 to access an isolated internal catheter lumen 66 and exit from the multiple flushing ports 12 (Fig. 2d). The enzyme may be, for example, a solution with 5 mg of rt-PA (Boehringer Ingelheim AG, Actilyse) and the solution may include the antithrombogenic agent heparin at 1000 IU. (Other substances such as antiagglutory prostaglandins or thromboxane receptor inhibitors may be employed to prevent restenosis, but are badly tolerated when given intravenously.) The enzyme dissolves the fractured thrombosis 56, and typically the enzyme and heparin are installed about the thrombosis for thirty minutes. After the treatment period, the enzyme may be removed from the treated region by way of the same ports 12 and lumen 66, and the region flushed with a solution of saline, heparin or the like, again by way of lumen 66 and ports 12.

Finally, the balloons 6, 8 can be deflated and the catheter removed (Fig. 2e). Hemostasis is obtained by manual compression applied in the usual manner.

As should be clear from the description, the method and apparatus described allows the treated region to be isolated. High concentrations of lytic enzyme may therefore be introduced for rapid, efficient and substantially complete dissolution of the fractured obstruction without the risk of raising systemic amounts of the enzyme to physiologically dangerous levels. It is also a feature of the invention that the pressure within the region near the obstruction is less than that of the systemic pressure in the regions 58 and 60 from which the balloon seals the treatment area. In this case, should small leakages occur around the periphery of the balloon, blood will tend to flow into the treatment area rather than the enzyme/heparin mixture flowing out into the bloodstream. As mentioned above, after treatment, the rt-PA may be removed through the flushing ports 12.

A double balloon catheter of the invention, having a distal balloon reinforced or nondistensible for dilation purposes and a second balloon from 2 to 50 cm proximal of the first balloon, was used to dilate and isolate the segment of the superficial femoral artery (SFA) as described. Through flushing ports between the balloons, 5 mg recombinant plasminogen activator (rt-PA, Boehringer Ingelheim) and heparin, 1000 IU was infused and enclosed for 30 minutes. The pressure in the isolated segment was less than arterial pressure and without pulsations, so that no rt-PA leaked. Thereafter the two balloons were deflated and the catheter was removed. Hemostasis was obtained by

compression. After the procedure 2000 IU heparin was given i.v., and heparin was continued for 24 hours.

Six patients with femoral artery occlusions (5 to 10 cm long) were recanalized with double balloon catheter thrombolysis. In no case did thrombosis reoccur within 30 days. All patients had a clinical benefit and a rise of the blood pressure on the ankle of 100%. The patients were relieved from their gangrene (3 patients), rest pain (2 patients) and claudication (1 patient).

These results are significantly better than our results with PTA on femoral artery occlusions ($p = 0.021$).

For comparison, the procedure described by Gruntzig and Hopft was carried out as concomitant aspirin and heparin was given. With regard to non-occluded stenotic lesions in the pelvic and femoral arteries the results were satisfactory. However, the results of recanalization of total occlusions in the superficial femoral artery (SFA) were poor. In fact, a total occlusion is a local thrombosis upon an intimal arteriosclerotic lesion. When such a lesion is dilated, the thrombotic material is displaced and fractured, which makes up a large thrombogenic surface. In accordance, within the first 24 hours thrombosis frequently reoccurs. After the first 24 hours the patency rate on occlusions did not differ from PTA treated stenosis.

Attempts were made, by infusing thrombolytic pharmacal into the artery, in order to dissolve chronic occlusions, but proved not to be effective and with a certain morbidity (local, gastrointestinal and intracerebral bleeding). These bleeding episodes are caused by the high accumulated dosage of lytic substance which is necessary in order to obtain an effective concentration of lytic substance and by the fact that the high infusion rate has to be given over many hours in remove the thrombosis.

Using the Gruntzig-Hopft procedure it is possible to obtain recanalization in only 60 to 70% after 24 hours, after 30 days about 50 to 60% of the vessels stay patent. Five years after the procedure only about 20% remain patent.

These results are far from satisfactory, and have caused that predominantly arterial stenosis and fewer occlusions are treated with PTA, and rarely veins are treated.

The method and apparatus of the invention also have obvious advantages to vascular surgery. The latter therapy carries the risk of serious complications, a mortality of 1 to 5%, postoperative ileus, bleeding and infection. In addition an in hospital stay from 10 to 30 days is usual and postoperatively some painful days are to be expected for the patient.

In contrast, few complications are involved with the double balloon catheter thrombolysis. Bleeding is only trivial at the arterial puncture site, and the in hospital stay rarely exceed 3 days.

Other embodiments are with in the following claims.

What is claimed is:

1. A method of treating a chronic occlusion in a blood vessel comprising providing a dilatation catheter having at least two spaced apart inflatable balloons, at least one of which is constructed to serve as a dilatation balloon, the catheter having means to separately inflate each balloon, inserting the catheter in the blood vessel and positioning the catheter so that the dilatation balloon corresponds to the region of the obstruction, inflating said dilatation balloon under conditions to cause dilatation of the thrombosed stenosed occlusion and exposure of dilated tissue while another balloon is not inflated to dilatation conditions, deflating said dilatation balloon and repositioning the catheter so that one of said balloons lies distal of and at least one other balloon lies proximal of the site at which dilatation has been performed, inflating both balloons sufficiently to isolate the dilated region from systemic blood flow, introducing via a lumen in said catheter, a bolus containing a fibrinolytic agent to the isolated space between said balloons, thus treating the dilated tissue with said agent to reduce the risk of clot formation or restenosis, and thereafter deflating said balloons and removing said dilatation catheter from the body.

2. The method of claim 1 wherein said fibrinolytic agent is rt-PA.

3. A dilatation balloon catheter adapted to be advanced through a passageway of a patient's body to the site of an occlusion, said catheter comprising:

an elongated, flexible catheter body having a distal region and a proximal end portion, and defining a plurality of lumens,

a first inflatable balloon disposed about said catheter body in said distal region, said first balloon formed of a nondistensible material,

a second inflatable balloon disposed about said catheter body and spaced proximally of said first balloon,

said catheter body and said balloons defining a treatment region generally between said first balloon and said second balloon,

a first lumen extending through said catheter body from an opening in said proximal end portion of the catheter body outside the patient's body to an opening within said first balloon,

means associated with said first lumen for delivering inflation fluid under pressure through said first lumen into said first balloon for inflation of said first balloon to a predetermined maximum diameter for dilatation treatment of a wall of a surrounding passageway,

a second lumen extending through said catheter body from an opening in said proximal end portion of the catheter body outside the patient's body to an opening within said second balloon,

means associated with said second lumen for delivering fluid under pressure through said second lumen into said second balloon for inflation of said second balloon to engage a wall of a surrounding passageway,

said catheter adapted to be positioned in a passageway with an occlusion, first subjected to dilatation treatment by inflation of said first balloon, disposed in said treatment region between said balloons,

said first balloon and said second balloon adapted to be inflated to engage the wall of a surrounding passageway, thereby to isolate the occlusion in said treatment region,

a third lumen extending through said catheter body from an opening in said proximal end portion of the catheter body outside the patient's body to a multiplicity of ports in said treatment region,

means associated with said third lumen for delivering a fibrinolytic agent through said third lumen into said treatment region by way of said multiple ports for treatment of the isolated section of the body passageway, and means associated with said third lumen for removal of the fibrinolytic agent from said treatment region through said third lumen by way of said multiple ports.

4. The dilatation catheter of claim 3 wherein said catheter body defines a fourth lumen extending through said catheter body from an opening in said proximal end portion of the catheter body outside the patient's body to an opening distal of said distal balloon, said catheter adapted to be advanced through the passageway of the patient's body to the site of an occlusion along a guidewire extending within said fourth lumen.

5. The dilatation catheter of claim 3 wherein said fibrinolytic agent is rt-PA.

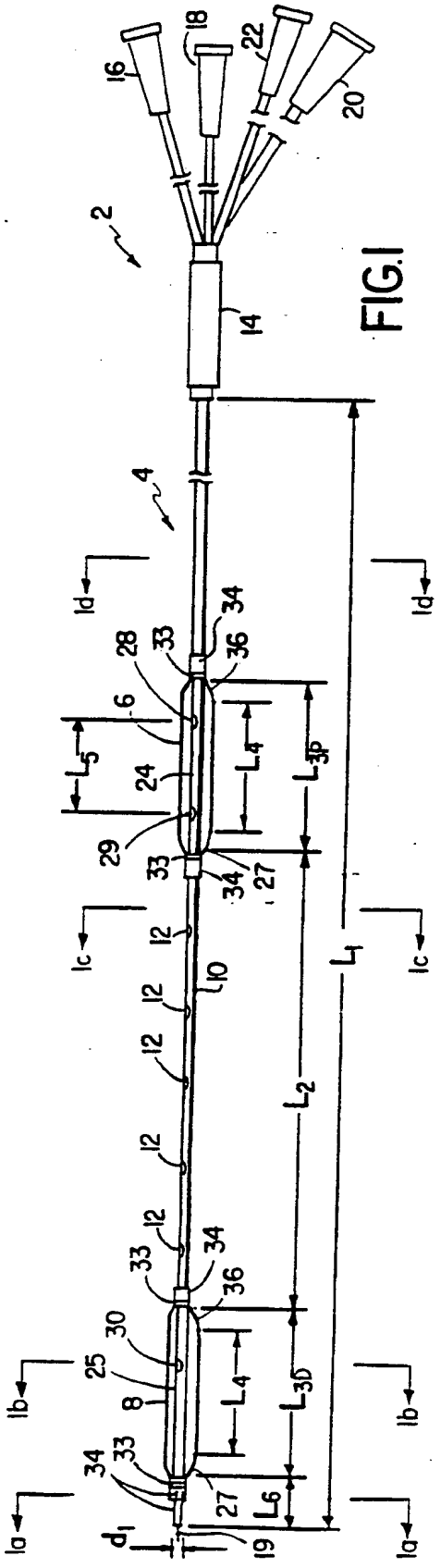

FIG.1

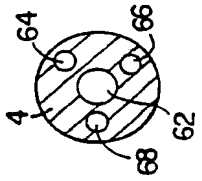

FIG.Id

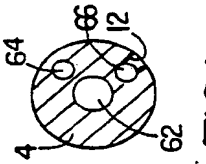

FIG.Ic

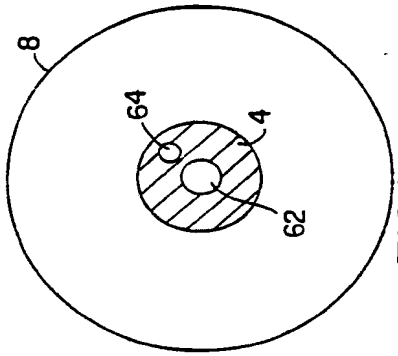

FIG.Ib

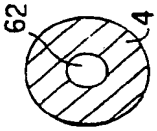

FIG.Ia

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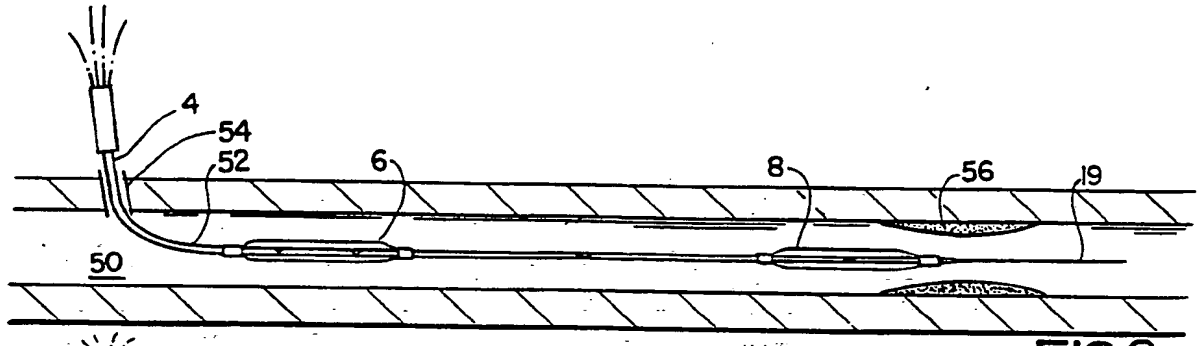

FIG 2

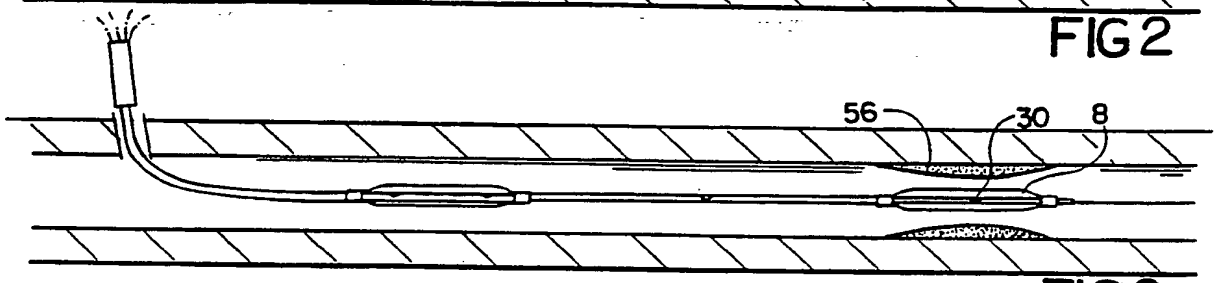

FIG 2a

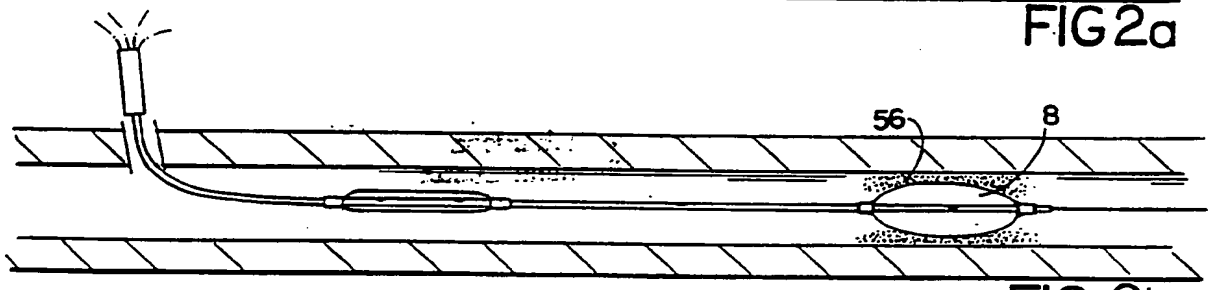

FIG 2b

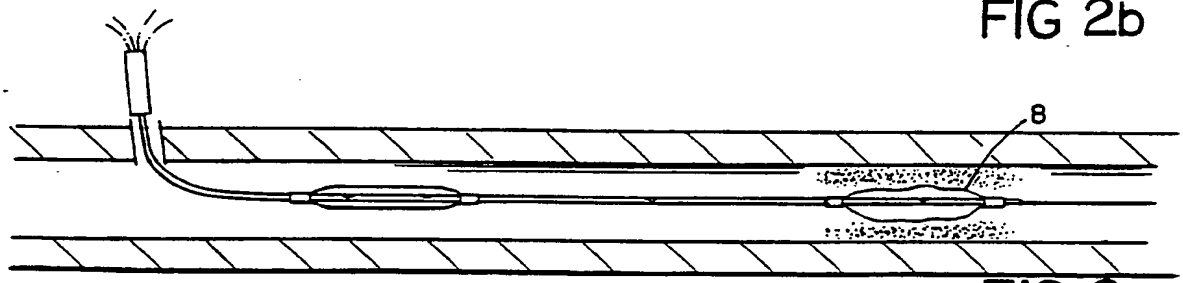

FIG 2c

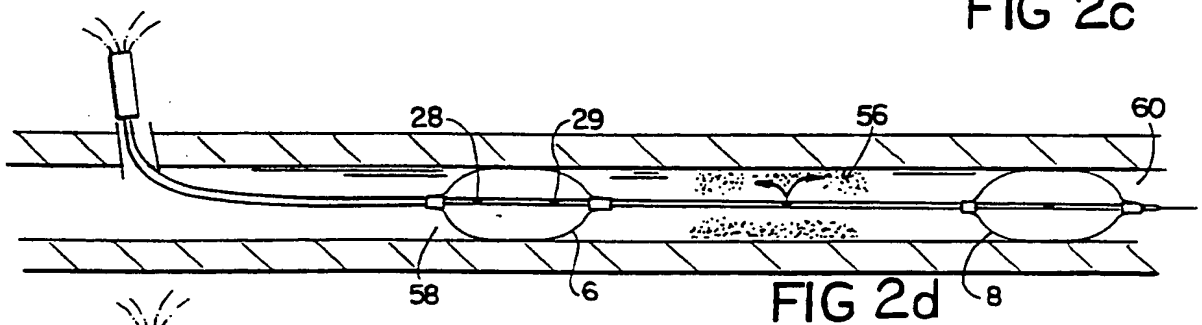

FIG 2d

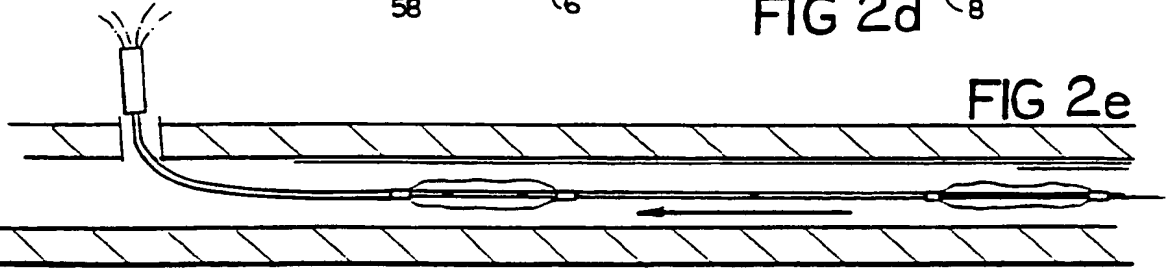

FIG 2e

INTERNATIONAL SEARCH REPORT

International Application No. PCT/US90/00083

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [6]

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC (5) A61 M 29/00
US CL 604/101

II. FIELDS SEARCHED

Minimum Documentation Searched [7]

Classification System	Classification Symbols
US	604/49-54, 101-103 514/822 606/159, 192-194

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched [8]

III. DOCUMENTS CONSIDERED TO BE RELEVANT [9]

Category *	Citation of Document, [11] with indication, where appropriate, of the relevant passages [12]	Relevant to Claim No. [13]
X, P X, P	US,A 4,824,436 (WOLINSKY) 25 APRIL 1989 See columns 3, line 63-column 4, line 7.	1-5
X Y	US,A 4,636,195 (WOLINSKY) 13 JANUARY 1987 See column 2, line 58-column 3, line 30	1-5
X Y	US,A 4,445,892 (HUSSEIN et al.) 01 MAY 1984 See entire document	1-5
X Y	US,A 4,573,966 (WEIKL et al.) 04 MARCH 1986 See abstract, Figs 1-11.	1-5
X Y	US,A 4,610,662 (WEIKL et al.) 09 SEPTEMBER 1986 See abstract, Figs. 1-11	1-5
A	US,A 4,723,549 (WHOLEY et al.) 09 FEBRUARY 1988 See column 1, lines 18-23	1-5

* Special categories of cited documents: [10]

"A" document defining the general state of the art which is not considered to be of particular relevance

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search

14 FEBRUARY 1990

Date of Mailing of this International Search Report

05 MAR 1990

International Searching Authority

ISA/US

Signature of Authorized Officer

MICHAEL RAFA Ngoc Ho Nguyen
HO NGUYEN

Form PCT/ISA/210 (second sheet) (Rev.11-87)

FURTHER INFORMATION CONTINUED FROM THE SECOND SHEET

Y,P	US,A 4,801,452 (HUNTER et al.) 31 JANUARY 1989 See column 1, lines 19-25	2,5

V. ☐ OBSERVATIONS WHERE CERTAIN CLAIMS WERE FOUND UNSEARCHABLE [1]

This international search report has not been established in respect of certain claims under Article 17(2) (a) for the following reasons:

1. ☐ Claim numbers . because they relate to subject matter [2] not required to be searched by this Authority, namely:

2. ☐ Claim numbers . because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out [3], specifically:

3. ☐ Claim numbers_____, because they are dependent claims not drafted in accordance with the second and third sentences of PCT Rule 6.4(a).

VI. ☐ OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING [2]

This International Searching Authority found multiple inventions in this international application as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims of the international application.

2. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims of the international application for which fees were paid, specifically claims:

3. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claim numbers:

4. ☐ As all searchable claims could be searched without effort justifying an additional fee, the International Searching Authority did not invite payment of any additional fee.

Remark on Protest

☐ The additional search fees were accompanied by applicant's protest.

☐ No protest accompanied the payment of additional search fees.